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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,044	10/29/2003	Robert M. Noack	00903/1/US	5857

7590 03/26/2007

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/696,044	NOACK ET AL.	
	Examiner	Art Unit	
	Micah-Paul Young	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-31 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 3/16/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Papers Received: Information Disclosure Statement dated 3/16/04.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,2,7-11,13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Morita et al (USPN 6,156,343 hereafter '343). The claims are drawn to a tablet formulation comprising a core. The core being surrounded by a water-soluble polymer and further being coated with an enteric polymer formulation comprising water-soluble pore formers.

3. The '343 patent teaches a controlled release tablet formulation comprising a core matrix and comprising water soluble polymer such as hydroxypropylcellulose and a binder such as magnesium stearate (Table 2). The core is coated with an enteric polymer such as hydroxypropylmethylcellulose phthalate (col. 5, lin. 58-63). The coating further includes water soluble pore-forming polymers such as hydroxypropylmethylcellulose (col. 4, lin. 15-18). Regarding the enteric polymers preventing a burst effect, it is the position of the Examiner that the polymers would inherently prevent a burst reaction based on their arrangement in the tablet formulation. For these reasons the claims are anticipated by the disclosures of the '343 patent.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Morita et al (USPN 6,156,343 hereafter '343). The claims are drawn to a method of making a controlled release formulation comprising granulating specific ingredients, forming a core and coating said core tablet.

7. As discussed above the '343 patent discloses a tablet formulation comprising a core matrix and coating. The reference discloses that the core ingredients are granulated and pressed into tablets and further coated with an enteric polymer solution (examples 1). The ingredients include hydroxypropylmethyl cellulose, a drug and magnesium stearate (examples). Te examples are silent to the inclusion of microcrystalline cellulose although microcrystalline cellulose is disclosed as being admixed into the core formulation (col. 6, lin. 61-68). The

examples use lactose although microcrystalline cellulose is disclosed as a functional equivalent diluent useful for the purposes of the invention.

8. It is the position of the Examiner that it would be well within the level of skill in the art to substitute a functional equivalent into a well known method. Barring a showing of unexpected results for the specific diluents of the instant claims, it is the position of the Examiner that such limitations do not impart patentability to the claims. One of ordinary skill in the art would have been motivated to include the microcrystalline cellulose into the formulation method with an expected result of a coated controlled release formulation.

9. Claims 1,3-6,12,15-25,30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Morita et al (USPN 6,156,343 hereafter '343) in view of Chao et al (US 2003/0073826 hereafter '826). The claims are drawn to a controlled release formulation comprising crystalline clindamycin free-base in the core.

10. As discussed above the '343 patent discloses controlled release tablet formulation comprising a core and enteric coating comprising water-soluble pore-forming polymers. The reference while disclosing various drugs is silent to the specific agent of the instant claims. Also the reference discloses various enteric polymers yet, is silent to the specific polymer recited in the claims.

11. Regarding the active agent and the enteric polymer, it is well within the level of skill in the art to include specific agents into a formulation as seen in the '826 patent. The '826 patent discloses a tablet formulation comprising crystalline clindamycin free-base (abstract). The tablet formulation comprises a core comprising up to 1000 mg of crystalline clindamycin free-base

[0050], [0081]. The core comprises disintegrants such as cellulose ethers, microcrystalline cellulose, pectin and karaya gum [0054]-[0055]. The core is coated with enteric polymers including polyvinyl acetate phthalate [0064]. The reference further provides a method of treating various infections with the crystalline free base clindamycin in humans [0080]. An artisan would have been motivated to include the components of the '826 patent in to the formulation of the '343 patent in order to have an improved control release of the antibiotic.

12. One of ordinary skill in the art would have been motivated to combine the antibiotic and enteric polymer of the '826 patent into the controlled release formulation of the '343 patent in order to better control the release of the antibiotic over a long period of time. It would have been obvious to do so with an expected result of a method of treating infection using an improved controlled release formulation.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Micah-Paul Young
Examiner
Art Unit 1618

MP Young

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER